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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/584,770   | 06/28/2006  | Ronit Sagi-Eisenberg | 27514U              | 5786             |
| 20529  | 7590        | 05/29/2008           |                     |                  |
| NATH & ASSOCIATES<br>112 South West Street<br>Alexandria, VA 22314 |             |                      | EXAMINER            |                  |
|  |             |                      | JUNG, UNSU          |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1641                |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/584,770

**Applicant(s)**

SAGI-EISENBERG, RONIT

**Examiner**

UNSU JUNG

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/86)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

1. Applicant's preliminary amendments to the specification and claim 16 and addition of new claim 32 dated June 28, 2006 have been acknowledged and entered.
2. Claims 1-32 are pending.

### ***Election/Restrictions***

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

#### List I: Rapamycin

1. Native rapamycin
2. Synthetically produced rapamycin
3. Analog of the above two (for this species, applicant is further required to specify a particular analog of the native or synthetically produced rapamycin)

#### List II: Sample

1. Liquid
  - a. Plasma
  - b. Blood/mammalian blood
  - c. Serum
  - d. Urine
  - e. Sperm
  - f. Cerebral spinal fluid
2. Solid/tissue
3. Semi solid
  - a. Tissues
  - b. Feces

#### List III: FKBP12 Protein

1. 12 kDa full FKBP12 protein

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2. Fragment of FKBP12 protein that maintains the rapamycin binding properties of the full protein (for this species, applicant is further required to specify a particular fragment of FKBP12 protein that maintains the rapamycin binding properties of the full protein)

List IV: FRB Fragment and Detectable Label

1. FRB fragment is directly bound to a detectable label
  - a. Colorimetry/enzyme
    - i. Alkaline phosphatase
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamine
      4. 3,3',5,5'-tetramethylbenzidine
    - ii. HRP enzyme
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamineb.
      4. 3,3',5,5'-tetramethylbenzidine
  - b. Spectrophotometry
  - c. Fluorospectrophotometry
  - d. Gaseometry
  - e. Radiospectrometry
2. FRB fragment is indirectly bound to a detectable label
  - a. Colorimetry/enzyme
    - i. Alkaline phosphatase
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamine
      4. 3,3',5,5'-tetramethylbenzidine
    - ii. HRP enzyme
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamineb.
      4. 3,3',5,5'-tetramethylbenzidine
  - b. Spectrophotometry
  - c. Fluorospectrophotometry
  - d. Gaseometry
  - e. Radiospectrometry

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

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must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

List I: Rapamycin (claim 2)

1. Native rapamycin
2. Synthetically produced rapamycin
3. Analog of the above two (for this species, applicant is further required to specify a particular analog of the native or synthetically produced rapamycin)

List II: Sample (claims 3-7)

1. Liquid (claims 3, 4, and 7)
  - a. Plasma (claims 3 and 4)
  - b. Blood/mammalian blood (claims 3, 4, and 7)
  - c. Serum (claims 3 and 4)
  - d. Urine (claims 3 and 4)
  - e. Sperm (claims 3 and 4)
  - f. Cerebral spinal fluid (claims 3 and 4)
2. Solid/tissue (claims 3 and 5)
3. Semi solid (claims 3 and 6)
  - a. Tissues
  - b. Feces

List III: FKBP12 Protein (claim 8)

1. 12 kDa full FKBP12 protein
2. Fragment of FKBP12 protein that maintains the rapamycin binding properties of the full protein (for this species, applicant is further required

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to specify a particular fragment of FKBP12 protein that maintains the rapamycin binding properties of the full protein)

List IV: FRB Fragment and Detectable Label (claims 14-19, 23-30)

1. FRB fragment is directly bound to a detectable label (claims 14, 16-19, and 23-26)
  - a. Coloremetry/enzyme (claims 14, 16-19 and 23-26)
    - i. Alkaline phosphatase
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamine
      4. 3,3',5,5'-tetramethylbenzidine
    - ii. HRP enzyme
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamine
      4. 3,3',5,5'-tetramethylbenzidine
  - b. Spectrophotometry (claims 14, 16, and 23)
  - c. Fluorospectrophotometry (claims 14, 16, and 23)
  - d. Gaseometry (claims 14, 16, and 23)
  - e. Radiospectrometry (claims 14, 16, and 23)
2. FRB fragment is indirectly bound to a detectable label (claims 15, 23-30, and 32)
  - a. Colorimetry/enzyme (claims 15, 23-30, and 32)
    - i. Alkaline phosphatase
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamine
      4. 3,3',5,5'-tetramethylbenzidine
    - ii. HRP enzyme
      1. p-nitrophenyl phosphate
      2. Hydrogen peroxide
      3. o-phenylenediamine
      4. 3,3',5,5'-tetramethylbenzidine
  - b. Spectrophotometry (claims 15, 23, 30, and 32)
  - c. Fluorospectrophotometry (claims 15, 23, 30, and 32)
  - d. Gaseometry (claims 15, 23, 30, and 32)
  - e. Radiospectrometry (claims 15, 23, 30, and 32)

The following claim(s) are generic: claims 1, 9-13, 20-22, and 31.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species listed above do

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not relate to single general inventive concept as the species do not have the same or corresponding special technical feature.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/  
Unsu Jung, Ph.D.  
Patent Examiner  
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